

Notice of Allowability

Application No.

10/077,406

Examiner

Eileen B. O'Hara

Applicant(s)

BROWNING ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 26 October 2007.
2. ☒ The allowed claim(s) is/are 54, 57, 58, 66, 59, 68-70, 92-94, 88, 89, 91, 71-77, 117-119, 79, 95, 114, 81-84, 96-98, 86, 99, 115, 100, 80, 87, 101-110, 116, 111, 60, 112, 113, 90, 120-137, renumbered as claims 1-74.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____:

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),

Paper No./Mail Date _____.

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____.

Eileen B. O'Hara
EILEEN B. O'HARA
PRIMARY EXAMINER

The present invention is directed to treatment of Th1 cell-mediated autoimmune disorders, and the instant specification teaches at paragraphs:

[0044] The term "Th1" refers to a subclass of T helper cells that produce LT-.alpha., interferon-gamma, and IL-2 (and other cytokines) and which elicit inflammatory reactions associated with a cellular, i.e. non-immunoglobulin, response to a challenge.

[0045] The term "Th2" refers to a subclass of T helper cells that produce cytokines, including IL-4, IL-5, IL-6 and IL-10, which are associated with an immunoglobulin (humoral) response to an immune challenge.

[0179] "Several systemic autoimmune diseases, including various arthritides, are Th1 cell-associated. Rheumatoid arthritis and Sjorgren's syndrome both appear to involve Th0 and Th1 cells. In contrast, systemic lupus erythematosus (SLE) appears to have an aberrant Th0/Th2 dominated response."

Therefore, US Patent No 7,255,854 and US Patent No 7,309,492 are directed to treatment of humoral, or Th2 mediated diseases/disorders, while the instant invention is directed to treatment of Th1 cell-mediated diseases/disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

The present invention is directed to treatment of Th1 cell-mediated autoimmune disorders, and the instant specification teaches at paragraphs:

[0044] The term "Th1" refers to a subclass of T helper cells that produce LT-.alpha., interferon-.gamma. and IL-2 (and other cytokines) and which elicit inflammatory reactions associated with a cellular, i.e. non-immunoglobulin, response to a challenge.

[0045] The term "Th2" refers to a subclass of T helper cells that produce cytokines, including IL-4, IL-5, IL-6 and IL-10, which are associated with an immunoglobulin (humoral) response to an immune challenge.

[0179] "Several systemic autoimmune diseases, including various arthritides, are Th1 cell-associated. Rheumatoid arthritis and Sjorgren's syndrome both appear to involve Th0 and Th1 cells. In contrast, systemic lupus erythematosus (SLE) appears to have an aberrant Th0/Th2 dominated response."

Therefore, US Patent No 7,255,854 and US Patent No 7,309,492 are directed to treatment of humoral, or Th2 mediated diseases/disorders, while the instant invention is directed to treatment of Th1 cell-mediated diseases/disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/077,406
Art Unit: 1646


Page 4

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner


EILEEN B. O'HARA
PRIMARY EXAMINER